California Department of Health Services

Request for Application

04-35199

Medi-Cal Clinical Laboratory Services

September 15, 2004

(Supersedes RFA released on April 5, 2004)

State of California—Health and Human Services Agency
Department of Health Services

California Department of Health Services

SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

September 15, 2004

Notice to Prospective Applicants

You are invited to review and respond to this Request for Application (RFA) Number 04-35199 entitled, "Medi-Cal Clinical Laboratory Services". In submitting your application, you must comply with the instructions found herein.

I. Application Submission Deadline

Regardless of postmark or method of delivery, the Department of Health Services' (DHS) Office of Medi-Cal Procurement must receive application packages no later than **4:00 p.m.** on **November 15, 2004**. Refer to the attached RFA for detailed submission requirements.

II. "Mandatory" Non-Binding Letter of Intent

In this procurement, prospective applicants are required to submit a non-binding mandatory Letter of Intent. See the RFA for detailed Letter of Intent submission instructions.

III. Applicant Questions

In the opinion of the California Department of Health Services, this Request for Application is complete and without need of explanation. However, if you have questions or need clarifying information, put all inquiries in writing and mail or fax them to DHS according to the instructions in the RFA section entitled, "Applicant Questions".

The RFA is available for electronic download in its entirety at the Office of Medi-Cal Procurement's website located at www.dhs.ca.gov/omcp. All Exhibits and Attachments contained in the electronic version of the RFA have been designed in a "fillable" format to allow for completion on a personal computer.

Thank you for your interest in DHS' service needs.

Sincerely,
Donna Martinez, Chief

Office of Medi-Cal Procurement
Attachment

Request for Application 04-35199

Medi-Cal Clinical Laboratory Services

California Department of Health Services
Office of Medi-Cal Procurement
MS4200
9800 Old Winery Place
Sacramento, CA 95827

Mailing: P.O. Box 997413
Sacramento, CA 95899-7413

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A. Purpose, Background and Description of Services

1. Purpose

The California Department of Health Services (DHS) is in the process of modifying and updating its Medi-Cal files and systems in order to assure that all providers seeking Medi-Cal reimbursement for clinical laboratory tests or examinations possess all required federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate(s) or registration(s), and have been, or are, issued a Medi-Cal clinical laboratory provider number.

Updating and modifying the Medi-Cal files and systems is being accomplished on a staggered basis and coordinated with the exercise of DHS' authority to contract with laboratories pursuant to Welfare and Institutions Code Section 14105.3. In order to coordinate the contracting process with updating and modifying the files and systems, contracting for clinical laboratory tests or examinations shall occur in stages.

The first opportunity to contract is being offered to clinical laboratories that possess an active Medi-Cal provider number for the performance of clinical laboratory tests or examinations classified as moderate or high complexity under CLIA. Specifically, this RFA applies to all those laboratories that provide moderate or high complexity clinical laboratory tests or examinations to, or for, fee-for-service Medi-Cal beneficiaries except for those clinical laboratories owned and operated by licensed clinics or health facilities, public health laboratories governed by the Health and Safety Code or physicians and physician groups billing for clinical laboratory tests or examinations with their physician or physician group Medi-Cal provider number. These providers are being offered the opportunity to respond to a Request for Application (RFA) to contract for clinical laboratory tests or examinations. Laboratories selected to contract must use their clinical laboratory provider number in order to seek reimbursement from the Medi-Cal program for moderate or high complexity clinical laboratory tests or examinations under the contract.

Clinical laboratory provider numbers shall reflect the location where the clinical laboratory tests or examinations are provided and for which the provider possesses the required CLIA certificate(s)/registration(s) and any required state clinical laboratory license(s).

Except as noted below, providers who are not awarded a contract under this RFA process shall no longer be able to seek reimbursement from the Medi-Cal program. This shall occur, regardless of whether the provider was previously issued a provider number.

If the provider of the moderate or high complexity clinical laboratory tests or examinations is a licensed clinic or health facility, a physician may be employed or perform clinical laboratory tests or examinations for that licensed clinic or health facility under the licensed clinic or health facility's CLIA certificate(s) and state clinical laboratory license(s) and registration(s) and the licensed clinic or health facility can continue to bill for these services under the clinic or health facility provider number.

If the provider of the moderate or high complexity clinical laboratory tests or examinations is a public health laboratory governed by the Health and Safety Code, the laboratory can continue to bill for these services under the public health laboratory's provider number provided that the

public health laboratory possesses the appropriate CLIA certificate(s) and state clinical laboratory license(s) or registration(s).

Likewise, physicians who are pathologists may continue to be employed or perform clinical laboratory tests or services for licensed clinical laboratory providers under the clinical laboratory's CLIA certificate(s) and state clinical laboratory license(s) or registration(s), and may continue to utilize their individual Medi-Cal provider number to bill Medi-Cal for the "professional component" of such services. In the future, DHS may issue pathology billing numbers for this purpose.

If the provider is a physician who possesses a waived or Provider Performed Microscopy Procedures (PPMP) CLIA certificate and any required state clinical laboratory registration and currently seeks reimbursement for the provision of only waived or PPMP clinical laboratory tests or examinations, he or she may continue to do so until notified by DHS that a clinical laboratory contract shall be required for their waived or PPMP clinical laboratory tests or examinations and how and when they will be offered the opportunity to apply.

Providers of clinical laboratory tests or examinations that are also licensed clinics or health facilities and, therefore, are not now being offered the opportunity to contract, may continue to seek reimbursement for all complexity levels of clinical laboratory tests or examinations, without entering into a contract, provided that the licensed clinic or health facility currently possesses the appropriate CLIA certificate(s) and state clinical laboratory license(s) or registration(s) and until such time as notified by DHS that a clinical laboratory contract shall be required and how and when they will be offered the opportunity to apply.

The Medi-Cal Clinical Laboratory Contracting Program intends to make contract awards to the most responsive and responsible applicants that agree to provide clinical laboratory tests or examinations to beneficiaries (Beneficiaries) of fee-for-service Medi-Cal and other non-managed care health care programs at the prices referenced in **Exhibit B, Attachment 1**, Reimbursement Rates.

2. Background

a. Medi-Cal Program

In July 1965, amendments to the Social Security Act, Title XVIII, established the Medicare program and Title XIX established the state-option Medical Assistance Program known as Medicaid, providing federal matching funds to states implementing a single comprehensive medical care program.

State legislation implementing the Title XIX program was signed in November of 1965. Medi-Cal, the California medical assistance Medicaid program, became effective March of 1966. Prior to the start of Medi-Cal, indigent Californians had been provided health care services through a variety of programs administered by the counties. With the advent of Medi-Cal, a wide range of health benefits was provided uniformly to those individuals throughout the State whose income and resources were insufficient to meet the costs of medical services without jeopardizing the person's or family's self-maintenance and security. Primarily, federal and state monies fund Medi-Cal. The federal government

generally contributes about 50 percent for the cost of most medical services provided to most beneficiaries currently covered by the program. With few exceptions, state government contributes the balance. The Medi-Cal program is administered by the State in cooperation with the federal and county governments.

b. Program Mission and Goals

Pursuant to Welfare and Institutions Code Section 14105.3 and at the discretion of DHS, the contracting process described in this RFA may be opened up to additional clinical laboratories in the future. DHS may enter into exclusive or nonexclusive contracts with laboratories for clinical laboratory tests or examinations for the purpose of obtaining the most favorable prices to the state and to assure adequate quality of the clinical laboratory tests or examinations. Only laboratories that meet the requirements of this RFA, including operation in conformity with Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code and the regulations adopted thereunder, and CLIA and the regulations adopted thereunder, may enter into a contract to provide clinical laboratory tests or examinations.

The major objective of this procurement is to issue contracts through the RFA process that ensure adequate access for Beneficiaries to quality clinical laboratory tests or examinations where contracting occurs at the most favorable prices to the State. The Medi-Cal program seeks to realize cost savings for clinical laboratory tests or examinations as a result of this procurement.

Additionally, a further objective of this procurement is to promote a higher level of ethical and lawful conduct in the clinical laboratory community and, in doing so, engage the clinical laboratories in reducing fraud and abuse within their organizations by requiring participation in the Clinical Laboratory Compliance Program.

In order to achieve maximum cost savings, the Legislature has determined that an expedited contract process for clinical laboratory tests or examinations is necessary. Therefore, contracts under this RFA are exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

B. Time Schedule

Below is the tentative time schedule for this procurement:

Event	**Date**	**Time (If applicable)**
Questions and Official Answers Released (for original RFA)	August 2, 2004	
Replacement RFA Released	**September 15, 2004**	
Replacement RFA Question Deadline	**September 24, 2004**	**4:00 p.m.**
Mandatory Non binding Letter of Intent due	**October 1, 2004**	**4:00 p.m.**

Event	Date Time (If applicable)
Replacement RFA Questions and Answers released	**October 8, 2004**
Application Due Date	**November 15, 2004 4:00 p.m. (PST)**
Notice of Award(s) Posted	February 1, 2005 (tentative)
Proposed Start Date of Contract	March 1, 2005 (tentative)

C. Contract Term

The term of the contract will be twenty-four **(24) months** and is anticipated to be effective March 1, 2005 through February 28, 2007 (tentative). The term of the agreement may change if DHS makes an award earlier than expected or if DHS cannot execute the agreement in a timely manner due to unforeseen delays.
Note: Please be advised that DHS expects a high volume of applications for this RFA which may extend the evaluation period beyond what has been anticipated. Please refer to OMCP's website at www.dhs.ca.gov/omcp for updates to the RFA event schedule.

The resulting contract will be of no force or effect until it is signed by both parties and approved by DHS. The Contractor is hereby advised not to commence performance of said contract until all approvals have been obtained; however, the provision of Medi-Cal clinical laboratory tests or examinations to Beneficiaries under the existing fee-for-service structure shall continue as usual until the commencement of the contracts under this RFA. The billing process for Medi-Cal clinical laboratory tests or examinations rendered will remain the same.

D. Applicant Questions

Immediately notify DHS if clarification is needed about the services sought or if questions arise about the RFA instructions or requirements. Put the inquiry in writing and transmit it to DHS as instructed below. At its discretion, DHS reserves the right to contact an inquirer to seek clarification of any inquiry received.

Applicants that fail to report a known or suspected problem with the RFA or fail to seek clarification and/or correction of the RFA shall submit an application at their own risk.

Following the question submission deadline, DHS will summarize all general questions and issues raised and mail or fax the summary and responses to all persons who received this RFA.

If an inquiry appears to be unique to a single Applicant or is marked "Confidential", DHS will mail or fax a response only to the inquirer if DHS concurs with the Applicant's claim that the inquiry is sensitive or proprietary in nature. If DHS does not concur, the inquiry will be answered in the manner described herein and the Applicant will be so notified. Inquiries and/or responses that DHS agrees should be held in confidence shall be held in confidence only until the Notice of Intent to Award is posted.

To the extent practical, inquiries shall remain as submitted. However, DHS may consolidate and/or paraphrase similar or related inquiries.

1. What to include in an inquiry

a. Name, title, name of the clinical laboratory, business address, mailing address if different, area code and telephone number, fax number and e-mail address, if applicable.
b. A description of the subject or issue in question or discrepancy found.
c. RFA section, page number or other information useful in identifying the specific problem or issue in question.
d. Remedy sought, if any.

An applicant that desires clarification about specific RFA requirements and/or whose inquiry relates to sensitive issues or proprietary aspects of an application may submit individual inquiries that are marked "Confidential". The Applicant must include with its inquiry an explanation as to why it believes questions marked "Confidential" are sensitive or surround a proprietary issue.

2. Question deadline

DHS will accept written or faxed inquiries received by **4:00 p.m. on September 24, 2004**. At its discretion, DHS may contact an inquirer to seek clarification of any inquiry received.

DHS will accept questions or inquiries about clarification of the services sought or RFA errors or irregularities if such inquiries are received prior to the Application submission deadline.

3. How to submit questions

Submit inquiries using one of the following methods:

U.S. Mail, Hand Delivery or Overnight Express:	**Fax:**
Questions RFA 04-35199 Department of Health Services Office of Medi-Cal Procurement Jesse Tanguileg 9800 Old Winery Place * Sacramento, CA 95827 P.O. Box 997413, MS 4200 Sacramento, CA 95899-7413 *No U.S. Mail delivery at this address	**Questions RFA 04-35199** Department of Health Services Office of Medi-Cal Procurement Jesse Tanguileg **Fax:** (916) 255-6126 **E-mail:** OMCPRFA7@dhs.ca.gov

Applicants submitting inquiries by fax or e-mail are responsible for confirming the receipt of all faxed materials by the question deadline.

Call Jesse Tanguileg at (916) 255-6032 to confirm faxed transmissions.

Applicant warning

DHS' internal processing of U.S. mail may add up to 48 hours or more to the delivery time. If mailing questions, consider using certified or registered mail and request a receipt upon delivery. If choosing hand delivery, allow sufficient time to locate the building and the visitor parking area and to sign-in at the security desk.

For driving and parking instructions, see **Appendix 9.**

4. Verbal questions

Verbal inquiries are discouraged. DHS reserves the right not to accept or respond to verbal inquiries. **Spontaneous verbal remarks provided in response to verbal inquiries are unofficial and are not binding on DHS unless later confirmed in writing.**

5. Pre-Application Conference

Not applicable. Please refer to Administrative Bulletin 8 (September 15, 2004) for more information.

E. Reasonable Accommodations

For individuals with disabilities, DHS will provide assistive services such as reading or writing assistance, and conversion of the RFA, questions/answers, RFA Addenda, or other Administrative Notices into Braille, large print, audiocassette, or computer disk. To request copies of written materials in an alternate format, please call the number below to arrange for reasonable accommodations.

Jesse Tanguileg
Office Of Medi-Cal Procurement
Telephone number (916) 255-6032
(TTY) California Relay telephone number 711-1-800-735-2929

NOTE: The range of assistive services available may be limited if requestors cannot allow ten or more State working days prior to the date the alternate format material is needed.

F. Mandatory Non-binding Letter of Intent

1. General information

Prospective Applicants that intend to submit an application are **required** to indicate their intention as to whether or not they intend to submit an application. A copy of the current CLIA certificate and, if not listed on the CLIA certificate, a copy of the current certification of

specialties and subspecialties **must** be submitted with the Mandatory Letter of Intent. **Use the Mandatory Letter of Intent (Attachment 8) for this purpose.**

IMPORTANT: Failure to submit the Mandatory Letter of Intent and required attachments will result in Application rejection and deactivation of the Medi-Cal provider number upon commencement of contracting.

The Mandatory Letter of Intent is not binding and prospective Applicants are not required to submit an application merely because a Letter of Intent is submitted.

2. Submitting a Letter of Intent

Regardless of delivery method, the Mandatory Letter of Intent must be received by **4:00 p.m. on October 1, 2004.**

Submit the Letter of Intent using one of the following methods:

U.S. Mail, Hand Delivery or Overnight Express:	**Fax:**
Letter of Intent RFA 04-35199 Department of Health Services Office of Medi-Cal Procurement Jesse Tanguileg 9800 Old Winery Place * Sacramento, CA 95827 P.O. Box 997413, MS 4200 Sacramento, CA 95899-7413 *No U.S. Mail delivery at this address	**Letter of Intent RFA 04-35199** Department of Health Services Office of Medi-Cal Procurement Jesse Tanguileg **Fax:** (916) 255-6126 **E-mail:** OMCPRFA7@dhs.ca.gov

Applicants transmitting a Letter of Intent by fax are responsible for confirming the receipt of the faxed Letter of Intent by the stated deadline.

Call Jesse Tanguileg at (916) 255-6032 to confirm faxed transmissions.

3. Applicant warning

DHS' internal processing of U.S. mail may add 48 hours or more to the delivery time. If mailing the Letter of Intent, consider using certified or registered or express mail. **Request a receipt confirming the delivery date and the time of delivery.** If choosing hand delivery, allow sufficient time to locate the visitor's parking area and to sign-in at the security desk.

For driving and parking instructions, see **Appendix 9**.

G. Scope of Work

See **Exhibit A** entitled, "Scope of Work" that is included in the Contract Forms and Exhibits section of this RFA. **Exhibit A** contains a detailed description of the services and activities to be performed as a result of this procurement. **Exhibit A** includes **Attachment 1** and **Attachment 2**, which are to be completed by the Applicant known as "Non-Solo Practitioner " and **Attachment 3** and **Attachment 4**, known as "Solo Practitioner ", giving a brief description on how the laboratory plans to implement the activities.

Note: See the Glossary **(Appendix 1)** for the definitions of "Non-Solo Practitioner" and "Solo Practitioner" if you have any questions regarding which Exhibit A Attachments should be completed based on your designation. Non-Solo Practitioner Clinical Laboratories should complete the questions contained in Exhibit A, Attachments 1 and 2 only, while Solo Practitioner Clinical Laboratories should complete the questions in Exhibit A, Attachments 3 and 4 only.

H. Qualification Requirements

Failure to meet the following requirements by the Application submission deadline will be grounds for DHS, in its sole discretion, to deem an applicant non-responsive. In submitting an application, each Applicant must certify and prove that it possesses the following qualification requirements.

1. Applicants must certify that they have read and agree to comply with all proposed terms and conditions addressed in Section "N" entitled, "Contract Terms and Conditions", including the terms appearing in the referenced contract exhibits.

2. Corporations must be in good standing and qualified to conduct business in California.

3. Applicants must possess a current Medi-Cal clinical laboratory provider number as issued by the Medi-Cal Provider Enrollment Branch of the California Department of Health Services. Applicants must meet the Medi-Cal Standards for Participation as described in Title 22, California Code of Regulations, commencing with Section 51200 **(See Appendix 4)** including the new Section 51200.01, Established Place of Business **(See Appendix 5).**

4. Applicants must meet the Conflict of Interest requirements as follows:

   a. Applicants must identify real or apparent conflicts of interest in accordance with **Attachment 9** - Conflict of Interest Compliance Certificate provisions and certify that no prohibited conflicts of interest exist.
   b. The Conflict of Interest Compliance Certificate will be incorporated into the contract awarded from this RFA and shall be in effect for the entire term of the contract.
   c. If a conflict of interest is determined to exist that cannot be resolved to the satisfaction of DHS before the award of the contract, the conflict will be grounds for deeming an application non-responsive.

5. The laboratory director(s) and owner(s) must certify that they, their spouses or dependent children and/or their employees have not:

a. Been convicted within the past ten (10) years, as defined in Business and Professions Code, Section 1321 and Welfare and Institutions Code Sections14043.36 and 14123, of the following:

   1) A criminal offense related to the delivery of an item or services under Medicare or Medicaid in any state;
   2) A conviction of any felony, or any misdemeanor involving fraud, abuse of the Medi-Cal program or neglect or abuse of any patient or beneficiary, or otherwise substantially related to the qualifications, functions, or duties of a provider of service;
   3) A conviction under federal or state law of a felony or misdemeanor related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct against a health care program financed by any federal, state, or local government agency;
   4) A conviction under federal or state law of a felony or misdemeanor relating to unlawful manufacturing, distributing, prescribing, or dispensing of a controlled substance;
   5) A conviction of any felony or misdemeanor involving fraud or abuse in any government program; and/or
   6) A conviction of a criminal offense in connection with the interference with or obstruction of any investigation into health care related fraud or abuse.

b. Been found liable for fraud or abuse in any civil proceeding, or entered into a settlement in lieu of conviction for fraud or abuse in any government program.
c. Been excluded, suspended, terminated or involuntarily withdrawn from a federal or state health care program.
d. Had a license, certificate or other approval to provide health care revoked, suspended, or excluded by a federal, California or other state's licensing, certification, or approval authority or has otherwise lost that license, certificate, or approval, or surrendered that license, certificate or approval while a disciplinary hearing on that license, certificate, or approval was pending.
e. Been found by any licensing, certifying, or professional standards board or agency to have violated the standards or conditions related to license, certification, or quality of care.
f. Failed to pay fines or overpayments assessed by the Medicare or Medicaid program,
g. Violated the Civil Monetary Penalties Law (42 U. S. C. Sec.1320a-7a) or the statute entitled "Criminal Penalties for Acts Involving Federal Health Care Programs" (42 U.S.C. Sec. 1320a-7b).
h. Owned or controlled an entity where a sanctioned individual or immediate family member (spouse, natural or adoptive parent, child, sibling, stepparent, stepchild, stepbrother or stepsister, in-laws, grandparent and grandchild) has held an ownership or controlling interest.

6. Applicants must be in compliance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 regarding security and privacy of protected health information and the use of industry-wide standards for health care information.

7. If Applicant has debt owing DHS, the Applicant must be making regular payments to reduce the debt.

I. Application Format and Content Requirements

1. General instructions

Each clinical laboratory that has an active Medi-Cal provider number and has met the qualification requirements listed in Section "H" above shall:

a. Submit only one Application per CLIA certificate.
b. Develop the Application by following all RFA instructions and/or clarifications issued by DHS in the form of question and answer notices, clarification notices, Administrative Bulletins or RFA addenda.
c. Before submitting an application, seek timely written clarification of any requirements or instructions that are believed to be vague, unclear or that are not fully understood.
d. In preparing an application response, make all narrative portions straightforward, detailed and precise. DHS will determine the responsiveness of an application by its content quality, not its volume, packaging or colored displays.
e. Arrange for the timely delivery of the Application package to the address specified in this RFA. Do not wait until shortly before the deadline to submit an application.
f. Ensure all required documents and certifications are submitted with the Application.

2. Format requirements

a. Submit one (1) original Application, two (2) redacted (See subsection 2(f) below) copies and five (5) copies, together with the original Application on one (1) CD ROM in any standard platform (i.e. Word, Excel or Adobe Acrobat). See 2(e) and 2(f) below for additional Application copy requirements.

   1) Write **"Original"** on the original Application.
   2) Write **"Redacted"** on the redacted copies. Please see **Appendix 1** entitled "Glossary of Terms" for definition.
   3) Each copy of the Application must be complete with a copy of all required attachments and documentation.

b. Format the narrative portion of the Application as follows:

   1) Use one-inch margins at the top, bottom, and both sides.
   2) Use a font size of not less than 12 points using the Arial font.
   3) Use a header and footer. Include in the header the name of the clinical laboratory in the upper left hand corner, RFA number in the upper right hand corner and the page number (1 of X) at the bottom of the page (centered).
   4) Print pages single-sided on white bond paper.
   5) Sequentially paginate the pages in each section. It is not necessary to paginate items in the Forms Section of the Application.
   6) All application materials must be prepared in **English** only.

Note: Fillable Adobe PDF versions of the Attachments and Exhibits are available on OMCP's website at www.dhs.ca.gov/omcp.

c. Bind each Application in a way that enables easy page removal. Loose leaf or three-ring binders are preferable.

d. All RFA attachments that require a signature must be signed in **blue** ink.

1) Have the person who is authorized to bind the proposing clinical laboratory as the sole proprietor, partner, corporate officer or government official sign each RFA attachment that requires a signature. The laboratory director as identified on the CLIA certificate must also sign each RFA attachment that requires a signature. Signature stamps are not acceptable.
2) Place the originally signed attachments in the appropriate Application set marked "Original".
3) The RFA attachments and other documentation placed in the extra application sets may reflect photocopied signatures.

e. **Do not mark any portion of the Application, any RFA attachment or other item of required documentation as "Confidential" or "Proprietary". DHS will disregard any language purporting to render all or portions of an application confidential.**

f. **Since all information and documentation are subject to disclosure pursuant to the Public Records Act, it is required that Applicants provide two (2) extra copies of the Application with all personal and confidential information redacted or blacked out (e.g. Social Security Number, home telephone number, etc.).**

3. Content Requirements

This section specifies the order and content of each Application. Assemble the materials in each Application set in the following order:

a. Application Cover Page

The person who is authorized to bind the proposing clinical laboratory as the sole proprietor, partner, corporate officer or government official must sign the Application Cover Page **(Attachment 1)**. The laboratory director as identified on the CLIA certificate must also sign **(Attachment 1)**.

b. Table of Contents

Properly identify each section and the contents therein. Paginate all items in each section with the exception of those items placed in the Forms Section.

c. Anti-Fraud Activities Section

1) Fiscal and Management Anti-Fraud Activities

In **Exhibit A, Attachments 1 & 3**, entitled "Fiscal and Management Anti-Fraud Activities", describe the clinical laboratory's plan to implement, upon contract commencement, the mandatory fiscal and management anti-fraud activities.

2) Clinical Laboratory Compliance Program

In **Exhibit A, Attachments 2 & 4,** entitled "Clinical Laboratory Compliance Program", describe the clinical laboratory's plan to implement, within ninety (90) days from contract commencement, the mandatory components of the Clinical Laboratory Compliance Program.

Important: See the Glossary **(Appendix 1)** for the definitions of "Non-Solo Practitioner" and "Solo Practitioner" Clinical Laboratory if you have any questions regarding which Exhibit A Attachments should be completed based on your designation. Non-Solo Practitioner Clinical Laboratories should complete the questions contained in Exhibit A, Attachments 1 and 2 only, while Solo Practitioner Clinical Laboratories should complete the questions in Exhibit A, Attachments 3 and 4 only.

For Exhibit A, Attachments 1, 2, 3 and 4, use only the form with the printed question and a maximum of one (1) additional sheet of paper for each question's response, and complete in accordance with the format requirements found in RFA section I.2.b, Format requirements. **Do not** attach copies of policy or procedure manuals. **All information contained on these forms is subject to the Public Records Act and may be subject to disclosure to the public.**

d. Project Personnel Section

Submit the following:

1) A copy of the most recent CLIA Laboratory Personnel Report – form HCFA 209. If there are any changes to the report, submit with appropriate additions and/or deletions, resigned and dated by the laboratory director.
2) A copy of the most recent State of California Laboratory Personnel Report - form LAB 116a. If there are any changes to the report, submit with appropriate additions and/or deletions, resigned and dated by the laboratory director.
3) The name, business address and telephone number of the person(s) or entity responsible for billing during the calendar year of 2003 and copies of contractual agreements, if any.
4) The name, business address and telephone number of the person(s) or entity responsible for obtaining new clients for the clinical laboratory and copies of contractual agreements, if any. Provide an explanation if the laboratory does not utilize such a person(s) or entity.
5) A list of all licensed practitioners who perform the professional component of clinical laboratory tests or examinations for the clinical laboratory. Separately identify those licensed practitioners who independently bill for the professional component of clinical laboratory tests or examinations utilizing the CLIA certificate of the Applicant.

6) The business name, address and CLIA number of any other clinical laboratory where the Applicant's laboratory director also serves as a laboratory director.
7) A copy of the laboratory director's current medical license or license as bioanalyst or director pursuant to Division 2, Chapter 3, Business and Professions Code.
8) A copy of the contractual agreement between the clinical laboratory and laboratory director if such agreement exists. If no contractual agreement exists, provide a specific explanation as to why there is no agreement.

e. Facilities, Resources and Equipment Section

1) Each Applicant shall submit a copy of the following:

a) Local business license.
b) California Clinical Laboratory License.
c) Lease agreement for the clinical laboratory's business address. If there is no agreement, submit name, address and telephone number of the property owner.
d) HIV testing authorization from the State of California, if HIV tests are performed.
e) The summary sheet that includes the proficiency test percent score for all regulated analytes for the calendar years 2002 and 2003.
f) List of ten third party payors as defined in the Glossary of Terms **(See Appendix 1)** from whom the clinical laboratory received payments during the period January through June 2004 and documentation to verify proof of payment.

2) If reference laboratories will be used to perform contract services, Applicants must identify any clinical laboratories used as a reference clinical laboratory during calendar year 2003. For each reference clinical laboratory, include the full name as shown on the CLIA certificate, the business address, telephone number of the clinical laboratory, and the CLIA certificate number.

3) Submit documents to support lease or ownership and maintenance of each item of clinical laboratory equipment, valued by the manufacturer to cost $50,000 or more, used to perform clinical laboratory tests or examinations, including but not limited to equipment serial numbers and those portions of the service agreements to document that equipment is in the lawful possession of the clinical laboratory and that clinical laboratory test or examination results are accurate and reliable. If no service agreement exists, describe the mechanism used by the clinical laboratory to maintain and repair the equipment identified.

f. Accessibility Section

Describe how accessible the clinical laboratory is to Beneficiaries. Include in the description the number of specimen collection sites owned and operated by the clinical laboratory and the location of each specimen collection site. Provide the approximate number of clinical laboratory tests or examinations performed annually by the clinical laboratory and approximately how many of those tests are provided to Beneficiaries.

g. Forms Section

Complete, sign and include the forms/attachments listed below. When completing the attachments, follow the instructions in this section and any instructions appearing on the attachment. After completing and signing the applicable attachments, assemble them in the order shown on the next page:

Attachment and/or Documentation	**Instructions**
2 - Required Attachment / Certification Checklist	Check each item with "Yes", and sign the form.
3 - Required Attachment Forms and Licenses	Check each item with "Yes" or "No", as applicable, and include all forms and licenses requested, and sign the form. As applicable, explain any responses on **Attachment 5** and include the corresponding number that is being referenced. DHS considers this a "qualified response". Any "qualified response" determined by DHS to be unsatisfactory or insufficient to meet a requirement, may cause an application to be deemed non-responsive.
4 - Required Attachment Certification of Qualifications	Check each item with "Yes" or "No", as applicable, and sign the form. As applicable, explain any responses on **Attachment 5** and include the corresponding number that is being referenced. DHS considers this a "qualified response". Any "qualified response" determined by DHS to be unsatisfactory or insufficient to meet a requirement, may cause an application to be deemed non-responsive.
5 – Justification	Completion of this Attachment is only required if justifying answers in **Attachment 3 and/or Attachment 4**.
6 – Applicant Information Sheet	Completion of the form is self-explanatory.
7 – Certification	Complete and sign this form indicating willingness and ability to comply with Contractor Certification Clauses appearing in this Attachment.
9 - Conflict of Interest Compliance Certification	Read carefully and sign this form. Submit with a plan if there are actual and/or potential conflicts of interest.
10 - Owner(s) and Laboratory Director(s) Agreement of Terms & Conditions	All owner (s) and laboratory director(s) must sign this form indicating their willingness to comply with the Terms and Conditions of this Application.

J. Application Submission

1. Application

a. Assemble an original, (2) redacted copies, five (5) copies and one (1) copy of the original Application on CD-ROM. Place the CD-ROM copy on top followed by the

Application set marked "Original", two (2) redacted copies and then the five (5) extra copies.

b. Please label the CD-ROM and storage case "Medi-Cal Clinical Laboratory Services Procurement 2004-2005", "The clinical laboratory's name", and "RFA 04-35199".

c. Place all Application copies in a single envelope or package, if possible. Seal the envelope or package.

If submitting more than one envelope or package, carefully label each one as instructed below and mark on the outside of each envelope or package "1 of X", "2 of X", etc.

d. Mail or arrange for hand delivery of the Application to DHS' Office of Medi-Cal Procurement (OMCP). Applications may not be transmitted electronically by fax or email.

e. OMCP must receive the Application, regardless of postmark or method of delivery, by **4:00 p.m. on November 15, 2004**. **Late Applications will not be accepted or reviewed.**

f. Label and submit the Application using one of the following methods:

Hand Delivery or Overnight Express:	**U.S. Mail:**
Application RFA 04-35199 Department of Health Services Office of Medi-Cal Procurement 9800 Old Winery Place Sacramento, CA 95827	**Application RFA 04-35199** Department of Health Services Office of Medi-Cal Procurement P.O. Box 997413, MS 4200 Sacramento, CA 95899-7413

g. **Applicant warning**

DHS' internal processing of U.S. mail may add up to 48 hours to the delivery time. If mailing the Application, consider using certified, registered or express mail. Request a return receipt confirming the delivery date and the time of delivery. If choosing hand delivery, allow sufficient time to locate the visitor parking area and to sign-in at the security desk.

For driving and parking instructions, **see Appendix 9.**

2. Proof of timely receipt

a. DHS staff will log and attach a date/time stamped slip or Application receipt to each Application package/envelope received. If an application envelope or package is hand delivered, DHS staff will give an application receipt to the hand carrier upon request.

b. To be timely, DHS' OMCP must receive each Application at the stated delivery address no later than **4:00 p.m.** on the Application submission due date. Neither delivery to the DHS mailroom or a U.S. postmark will serve as proof of timely delivery.

c. **DHS will <u>not</u> accept late Applications.**

3. Applicant costs

Applicants are responsible for all costs of developing and submitting an application.

K. Evaluation and Selection

The primary objective of evaluation and selection is to award contracts to the Applicants who have best demonstrated the ability, capability, and willingness to meet all of the contract requirements. Emphasis is placed on an applicant's provision of quality clinical laboratory tests or examinations that meet professionally recognized standards of health care to Medi-Cal beneficiaries, and on an applicant's ability to perform the required anti-fraud activities and implement a written comprehensive Clinical Laboratory Compliance Program.

Evaluation and selection will consist of multiple stages as detailed below. The evaluation process will be used to review and/or score applications. DHS will, at its sole discretion, reject any application that is found to be non-responsive at any stage of evaluation. An evaluation committee will be used for all stages of the evaluation and selection process. The evaluation committee is comprised of four groups:

- The **Preliminary Review Committee (PRC)** consists of team leads from the OMCP and the Medi-Cal Policy Division and conducts Stage 1 review.

- The **Evaluation Scoring Committee (ESC)** consists of MCPD staff and DHS staff working in other areas of the Medi-Cal program. The ESC is responsible for the review of applications.

- The **Rating Review Committee (RRC)** consists of OMCP management staff and members of the PRC. The RRC will interact with the ESC throughout the evaluation process.

- The **Executive Review Committee (ERC)** consists of DHS management officials. The ERC may, at the members' discretion review evaluation and selection processes and recommended scores for each application throughout the procurement process. This review is to assure all appropriate procedures and processes have been followed. Additionally, the ERC may seek independent review or advice from individuals within DHS or elsewhere regarding procurement policy matters, technical and/or cost application deficiencies, and acceptability.

1. **Stage 1—Reviewing Required Attachment/Certification Checklist, Attachment 2**

   a. Shortly after the application submission deadline, the PRC will convene to review each application for timeliness, completeness and initial responsiveness to the RFA requirements. This is a pass/fail evaluation.

   b. In this review stage, the PRC will compare the contents of each application to the claims made by the Applicant on the Required Attachment/Certification Checklist, Attachment 2 to determine if the Applicant's claims are accurate and all required documents are included.

   c. While it is incumbent upon the Applicant to ensure that all required forms, data, information, etc. are complete, correct and signed (if required) when submitting the application, the PRC may collect a missing signature(s) on an otherwise complete and correct required form(s), information, etc.

   d. If an Applicant's claims on the Required Attachment/Certification Checklist, Attachment 2 cannot be proven or substantiated, or if an Applicant omits a required document, form, attachment, information, etc. (other than a signature), DHS will deem the application non-responsive and rejected from further consideration.

2. **Stage 2—Reviewing Required Forms and Licenses (Attachment 3) and Certification of Qualifications (Attachment 4)**

   a. The ESC will individually and/or as a team review and evaluate applications that have passed Stage 1 review.

   b. In this review stage, the ESC will evaluate the Required Forms and Licenses (Attachment 3) and the Certification of Qualifications (Attachment 4) to determine the adequacy of the Applicant's submissions. This is a pass/fail review.

   c. While it is incumbent upon the Applicant to ensure that all required forms, data, information, etc. are complete, correct and signed (if required) when submitting the application, the ESC may collect a missing signature(s) on an otherwise complete and correct required form(s), information, etc.

   d. If an Applicant's submitted answers, data or information on Attachments 3 and/or 4 are inadequate or missing, DHS will deem the application non-responsive and rejected from further consideration.

3. **Stage 3—Point-Scoring the Application**

   a. The ESC will individually and/or as a team review and evaluate applications based on their adequacy, thoroughness, and the degree to which they comply with the RFA requirements.
   b. The ESC will use the scoring system detailed in the chart below to assign points. Following this chart is a list of considerations that the ESC may take into account when assigning points to an application.

Points	Interpretation	General basis for point assignment
0	**Inadequate**	Application response (i.e. content and/or explanation offered) is inadequate or does not meet DHS' needs/requirements or expectations. The omission(s), flaw(s) or defect(s) are significant and unacceptable.
1	**Barely Adequate**	Application response (i.e. content and/or explanation offered) is barely adequate or barely meets DHS' needs/requirements or expectations. The omission(s), flaw(s) or defect(s) may be consequential but are acceptable.
2	**Adequate**	Application response (i.e. content and/or explanation offered) is adequate or meets DHS' needs/requirements or expectations. The omission(s), flaw(s) or defect(s), if any, are inconsequential and acceptable.
3	**More than Adequate**	Application response (i.e. content and/or explanation offered) is more than adequate or fully meets DHS' needs/requirements or expectations. Minimal weaknesses are acceptable.
4	**Excellent or Outstanding**	Application response (i.e. content and/or explanation offered) is well above average or exceeds DHS' needs/requirements or expectations. Applicant offers one of more enhancing features, methods or approaches that will enable performance to exceed DHS' basic expectations.

c. In assigning points for individual evaluation questions, the ESC may consider issues including, but not limited to the extent to which an application response:

   1. Is lacking information, lacking depth or breadth or lacking significant facts and/or details, and/or

   2. Is fully developed, comprehensive and has few if any weaknesses, defects or deficiencies, and/or

   3. Demonstrates that the Applicant understands DHS' needs, the services sought, and/or the contractor's responsibilities, and/or

   4. Illustrates the Applicant's capability to perform all services and meet all scope of work requirements, and/or

   5. If implemented, will contribute to the achievement of DHS' goals and objectives, and/or

   6. Demonstrates the Applicant's capacity, capability and/or commitment to exceed regular service needs (i.e. enhanced features, approaches or methods; creative or innovative business solutions).

d. The evaluation questions in this stage are broken into two sections; Fiscal and Management Anti-Fraud Activities, and Compliance Program. Each question will be assigned points ranging from 0 to 4. There is also a weight value applied to points earned in each of the two sections. Below are the point values and weight values for

each section that will be scored. Calculations shall result in numbers being rounded to two (2) decimal places.

Applications will be scored on a scale of 0 to 120 points, as follows:

Section	# of ?	Points Available	X	Weight	=	Total Points Possible
Fiscal and Management Anti-Fraud Activities Exhibit A, Attachment 1 **or** 3	18	72	X	1.0	=	72
Compliance Program Exhibit A, Attachment 2 **or** 4	6	24	X	2.0	=	48
Grand Total Points Possible = 120						

4. Stage 4—Final Score Calculation

An applicant's final score will equal their Grand Total points achieved:

Section	Total Points Earned	X	Weight	=	Subtotal Points Earned
Fiscal and Management Anti-Fraud Activities (Non-Solo Practitioner **or** Solo Practitioner)		X	1.0	=	
Compliance Program (Non-Solo Practitioner **or** Solo Practitioner)		X	2.0	=	

The two subtotals of points earned are then added together to compute the Grand Total points achieved (final score).

DHS will create a tally sheet, listing all applicants and their final scores. **Only Applicant's that achieve a minimum score of 30.00 will be awarded contracts.**

L. Application Questions

1. Fiscal and Management Anti-Fraud Activities Section – NON-SOLO PRACTITIONER (Exhibit A, Attachment 1)

Activity 1 **1. To what extent does the Applicant's response ensure that clinical laboratory tests ordered by licensed practitioners are monitored in a manner that detects potential ordering abuses?**	**Points Awarded (0-4)**
1.1 To what extent does the mechanism described ensure that Activity 1 will be accomplished?	
1.2 To what extent does the submitted documentation ensure that Activity 1 will be accomplished?	
1.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 1 will be accomplished?	
Activity 2 **2. To what extent does the Applicant's response ensure that the clinical laboratory bills for only those clinical laboratory tests or examinations ordered by the licensed practitioner? To what extent does the Applicant's response ensure that the clinical laboratory will ensure that written orders are obtained within thirty (30) calendar days or that efforts will be made to obtain a written authorization in compliance with Title 41, CFR 493.1105?**	**Points Awarded (0-4)**
2.1 To what extent does the mechanism described ensure that Activity 2 will be accomplished?	
2.2 To what extent does the submitted documentation ensure that Activity 2 will be accomplished?	
2.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 2 will be accomplished?	
Activity 3 **3. To what extent does the Applicant's response ensure that, prior to billing, the clinical laboratory verifies with the licensed practitioner the actual test or examination that the licensed practitioner wants performed when a specimen is received without a valid test order or with an ambiguous test order?**	**Points Awarded (0-4)**
3.1 To what extent does the mechanism described ensure that Activity 3 will be accomplished?	

3.2 To what extent does the submitted documentation ensure that Activity 3 will be accomplished?	
3.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 3 will be accomplished?	
Activity 4 **4. To what extent does the Applicant's response ensure that the clinical laboratory or its billing department does not utilize an inappropriate code or does not upcode by selecting a CPT code to obtain maximum reimbursement when such CPT code is not the most appropriate descriptor of the clinical laboratory test or examination or if all tests in an Organ and Disease Oriented Panel as defined in the CPT were not performed ?**	**Points Awarded (0-4)**
4.1 To what extent does the mechanism described ensure that Activity 4 will be accomplished?	
4.2 To what extent does the submitted documentation ensure that Activity 4 will be accomplished?	
4.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 4 will be accomplished?	
Activity 5 **5. To what extent does the Applicant's response ensure that the clinical laboratory will contact the ordering licensed practitioner to obtain specific ICD-9 or Family PACT specific "S" diagnosis code information for each clinical laboratory test or examination ordered in the event that such information has not been provided? To what extent does the Applicant's response ensure that the clinical laboratory or its billing department will maintain documentation of the provider contacts initiated to obtain the information and how any ICD-9 or Family PACT specific "S" diagnosis code information provided is documented?**	**Points Awarded (0-4)**
5.1 To what extent does the mechanism described ensure that Activity 5 will be accomplished?	
5.2 To what extent does the submitted documentation ensure that Activity 5 will be accomplished?	
5.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 5 will be accomplished?	

Activity 6 **6. To what extent does the Applicant's response ensure that clinical laboratory tests or examinations are not billed for specimens that are received in an aged or otherwise deteriorated condition? To what extent does the Applicant's response ensure that technical assistance will be provided to the person or entity that submitted the aged or otherwise deteriorated specimens before additional specimens received from the person or entity are billed to the program? To what extent does the Applicant's response ensure that if compromised specimens are again obtained or otherwise provided from the person or entity, the clinical laboratory will ensure that no clinical laboratory tests or examinations ordered by this person or entity are billed under this contract until uncompromised specimens are received and accurate, reliable results are ensured?**	**Points Awarded (0-4)**
6.1 To what extent does the mechanism described ensure that Activity 6 will be accomplished?	
6.2 To what extent does the submitted documentation ensure that Activity 6 will be accomplished?	
6.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 6 will be accomplished?	
Fiscal and Management Anti-Fraud Activities Total Points _____ X 1.0 =_____	

2. Clinical Laboratory Compliance Program Section – NON-SOLO PRACTITIONER (Exhibit A, Attachment 2

Activity Number/Question	**Points Awarded (0-4)**
1. To what extent does the Applicant describe/explain its plan to develop Standards of Conduct; as well as written policies and procedures promoting the clinical laboratory's commitment to compliance when addressing specific areas of potential fraud, waste and abuse, including but not limited to CPT coding issues, improper ICD-9 or Family PACT specific "S" diagnosis coding and improper claims submissions?	
2. To what extent does the Applicant describe/explain its plan to designate a compliance officer and compliance committee who are responsible for operating and monitoring the compliance program and who report directly to the laboratory director?	

3. To what extent does the Applicant describe/explain its plan to develop policies to ensure it does not employ, contract or submit claims for individuals listed on the Suspended or Ineligible Provider List published by DHS to identify suspended and otherwise ineligible providers or is a person or entity listed on any list published by the federal DHHS Office of the Inspector General regarding the suspension or exclusion of individuals or entities from the federal Medicare and Medicaid programs, to identify suspended, excluded or otherwise ineligible providers? (refer to Exhibit A Scope of Work subsection 6(b)(3))	
4. To what extent does the Applicant describe/explain its plan to maintain a process to receive complaints, including posting the Medi-Cal Fraud Hotline telephone numbers in conspicuous places visible to clinical laboratory employees in the laboratory and visible to Beneficiaries in the specimen collection sites owned and operated by the clinical laboratory?	
5. To what extent does the Applicant describe/explain its plan to develop and implement regular, effective education, training and retraining programs for all employees providing services to Beneficiaries or billing the Medi-Cal program and to management regarding the requirements of the Medi-Cal program?	
6. To what extent does the Applicant describe/explain its plan to conduct internal monitoring and auditing to evaluate compliance and assist in the reduction of identified problem areas?	
Clinical Laboratory Compliance Program Total Points _____ X 2.0 = _____	

3. Fiscal and Management Anti-Fraud Activities Section – SOLO PRACTITIONER (Exhibit A, Attachment 3)

Activity 1 **1. To what extent does the Applicant's response ensure that only medically necessary tests are billed to the Medi-Cal program?**	**Points Awarded (0-4)**
1.1 To what extent does the mechanism described ensure that Activity 1 will be accomplished?	
1.2 To what extent does the submitted documentation ensure that Activity 1 will be accomplished?	
1.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 1 will be accomplished?	

Activity 2 **2. To what extent does the Applicant's response ensure that the written order is reflected in the patient's chart or medical record and how that information is available to the staff member performing the test at the time of the testing and available to the staff member(s) responsible for billing?**	**Points Awarded (0-4)**
2.1 To what extent does the mechanism described ensure that Activity 2 will be accomplished?	
2.2 To what extent does the submitted documentation ensure that Activity 2 will be accomplished?	
2.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 2 will be accomplished?	
Activity 3 **3. To what extent does the Applicant's response ensure that any ambiguous test orders are clarified prior to billing?**	**Points Awarded (0-4)**
3.1 To what extent does the mechanism described ensure that Activity 3 will be accomplished?	
3.2 To what extent does the submitted documentation ensure that Activity 3 will be accomplished?	
3.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 3 will be accomplished?	
Activity 4 **4. To what extent does the Applicant's response ensure that the staff member(s) responsible for billing does not utilize an inappropriate code or does not upcode by selecting a CPT code to obtain maximum reimbursement when such CPT code is not the most appropriate descriptor of the clinical laboratory tests or examination or if all tests in an Organ and Disease Oriented Panel as defined in the CPT were not performed?**	**Points Awarded (0-4)**
4.1 To what extent does the mechanism described ensure that Activity 4 will be accomplished?	
4.2 To what extent does the submitted documentation ensure that Activity 4 will be accomplished?	
4.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 4 will be accomplished?	

Activity 5 **5. To what extent does the Applicant's response ensure that the staff member(s) responsible for billing, assures that the correct ICD-9 or Family PACT specific "S" diagnostic code information is included on each claim form submitted to the Medi-Cal program?**	**Points Awarded (0-4)**
5.1 To what extent does the mechanism described ensure that Activity 5 will be accomplished?	
5.2 To what extent does the submitted documentation ensure that Activity 5 will be accomplished?	
5.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 5 will be accomplished?	
Activity 6 **6. To what extent does the Applicant's response ensure that clinical laboratory tests or examinations are not billed for specimens that have become aged or otherwise deteriorated? To what extent does the Applicant's response ensure that technical assistance will be provided to the person that allowed the specimen to become aged or otherwise deteriorated?**	**Points Awarded (0-4)**
6.1 To what extent does the mechanism described ensure that Activity 6 will be accomplished?	
6.2 To what extent does the submitted documentation ensure that Activity 6 will be accomplished?	
6.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 6 will be accomplished?	
Fiscal and Management Anti-Fraud Activities Total Points _____ X 1.0 =_____	

4. Clinical Laboratory Compliance Program Section – SOLO PRACTITIONER (Exhibit A, Attachment 4)

Activity Number/Question	**Points Awarded (0-4)**
1. To what extent does the Applicant describe/explain its plan to develop Standards of Conduct; as well as written policies and procedures promoting the clinical laboratory's commitment to compliance when addressing specific areas of potential fraud, waste and abuse, including but not limited to CPT coding issues,	

improper ICD-9 or Family PACT specific "S" diagnosis coding and improper claims submissions?	
2. To what extent does the Applicant describe/explain how the laboratory director shall be responsible for the operation and monitoring of the compliance program?	
3. To what extent does the Applicant describe/explain its plan to develop policies to ensure it does not employ, contract or submit claims for individuals listed on the Suspended or Ineligible Provider List published by DHS to identify suspended and otherwise ineligible providers or is a person or entity listed on any list published by the federal DHHS Office of the Inspector General regarding the suspension or exclusion of individuals or entities from the federal Medicare and Medicaid programs, to identify suspended, excluded or otherwise ineligible providers? (refer to Exhibit A Scope of Work subsection 6(b)(3))	
4. To what extent does the Applicant describe/explain its plan to maintain a process to receive complaints, including posting the Medi-Cal Fraud Hotline telephone numbers in conspicuous places visible to clinical laboratory employees in the laboratory and visible to Beneficiaries in the specimen collection sites owned and operated by the clinical laboratory?	
5. To what extent does the Applicant describe/explain its plan to develop and implement regular, effective education, training and retraining programs for all employees providing services to Beneficiaries or billing the Medi-Cal program and to management regarding the requirements of the Medi-Cal program?	
6. To what extent does the Applicant describe/explain its plan to conduct internal monitoring and auditing to evaluate compliance and assist in the reduction of identified problem areas?	
Clinical Laboratory Compliance Program Total Points _____ X 2.0 = _____	

M. Application Requirements and Information

1. Non-responsive Applications

In addition to any condition previously indicated in this RFA, the following occurrences **will** cause DHS to deem an application non-responsive:

a. Failure of an applicant to:

1) Meet Application format/content or submission requirements including, but not limited to, the sealing, labeling, packaging and/or timely and proper delivery of Applications.

2) Not documenting explanations in **Attachment 5**.

3) Submit a **Mandatory** Letter of Intent (**Attachment 8**) and required attachments in the manner required. Attachments include:

   a) CLIA certificate
   b) Current certification of specialties and subspecialties

4) Submit a **mandatory** Conflict of Interest Compliance Certificate (**Attachment 9**) in the manner required.

5) Submit Owner(s) and Laboratory Director(s) Agreement of Terms & Conditions (**Attachment 10)** with appropriate names and signatures.

6) **Use the correct RFA documents.**

   Important: The original RFA released on April 5, 2004 and all associated addenda issued <u>prior</u> to the release of this replacement RFA on September 15, 2004 should be discarded in its entirely. Only documents from this replacement RFA and any subsequently issued addenda should be used in the preparation of your application.

b. If an applicant submits an application that is conditional, materially incomplete or contains material defects, alterations or irregularities of any kind.

c. If an applicant supplies false, inaccurate or misleading information or falsely certifies compliance on any RFA attachment.

d. If DHS discovers, at any stage of the RFA process or upon contract award, that the Applicant is unwilling or unable to comply with the contract terms, conditions and exhibits cited in this RFA or the resulting contract.

e. If other irregularities occur in an application response that is not specifically addressed herein (i.e., the Applicant places any conditions on performance of the scope of work, submits a counter Application, etc.).

2. Application modifications after submission

a. All Applications are to be complete when submitted. However, an entire Application may be withdrawn and the Applicant may resubmit a new Application prior to the submission deadline.

b. To withdraw and/or resubmit a new Application, follow the instructions appearing in the RFA section entitled, “Withdrawal and/or Resubmission of Applications”.

3. Withdrawal and/or Resubmission of Applications

a. Withdrawal Deadline

An applicant may withdraw an application at any time before the Application submission deadline.

b. Withdrawal after Deadline

With the consent of DHS, an application may be withdrawn after the Application submission deadline. An application withdrawn after the submission deadline may not be resubmitted or replaced by a newly submitted Application.

c. Submitting a Withdrawal Request

1) Submit a written withdrawal request, signed by an authorized representative of the Applicant.

2) Label and submit the withdrawal request using one of the following methods:

U.S. Mail, Hand Delivery or Overnight Express:	**Fax:**
Withdrawal RFA 04-35199 Department of Health Services Office of Medi-Cal Procurement 9800 Old Winery Place * Sacramento, CA 95827 P.O. Box 997413, MS 4200 Sacramento, CA 95899-7413 *No U.S. Mail delivery at this address	**Withdrawal RFA 04-35199** Department of Health Services Office of Medi-Cal Procurement **Fax:** (916) 255-6126

3) **[For faxed withdrawal requests]** Applicants must call (916) 255-6126 to confirm receipt of a faxed withdrawal request. Follow-up the faxed request by mailing or delivering the signed original withdrawal request within 24 hours after submitting a faxed request.

An originally signed withdrawal request is generally required before DHS will return an application to an applicant. DHS may grant an exception if the Applicant informs DHS that a new or replacement Application will immediately follow the withdrawal.

d. Resubmitting an application

If an applicant is withdrawing an application before the Application submission deadline, the Applicant may resubmit a new Application according to the Application submission instructions. Replacement Applications must be received at the stated place of delivery by the Application due date and time.

4. Contract award

a. Award of the contracts, if awarded, shall be to the responsive and responsible Applicants that have received a pass rating in Stage 1 and 2, and achieved a minimum score of 30.00 in Stage 4.

b. DHS will award the contracts only after DHS posts a Notice of Intent to Award. DHS tentatively expects to post the Notice of Intent to Award before the close of business **February 1, 2005** on the OMCP website at www.dhs.ca.gov/omcp and at the following location:

Department of Health Services
Contract Management Unit
1501 Capitol Avenue, First Floor Guard Station
Sacramento, CA 95814

c. DHS may mail or fax a written notification and/or a copy of the Notice of Intent to Award that lists all laboratories that have been awarded a contract.

d. DHS will confirm the contract awards to the Applicants. DHS staff may confirm an award verbally or in writing.

5. Disposition of Applications

a. All materials submitted in response to this RFA will become the property of the Department of Health Services and, as such, are subject to the Public Records Act (Government Code Section 6250, et seq.). **It is DHS' intent to use submitted redacted Applications for such requests.** DHS will disregard any language purporting to render all or portions of any Application confidential.

b. Applications are public records upon the opening and reading of the Applications. However, the contents of all Applications, draft RFAs, correspondence, agendas, memoranda, working papers, or any other mediums which disclose any aspect of an application shall be held in the strictest confidence until the award is made.

6. Inspecting or obtaining copies of Applications

a. Who can inspect or copy Application materials?

Any person or member of the public can inspect or obtain copies of any Application materials.

b. What can be inspected / copied and when?

1) After DHS posts the Notice of Intent to Award the RFA, any existing Applicants List (i.e. the listing of laboratories to whom the RFA was sent) is considered a public record and will be available for inspection or copying.

2) On or after the date DHS posts the Notice of Intent to Award, all Applications, Letters of Intent, checklists, pass/fail and or scored evaluation sheets become public records. These records shall be available for review, inspection and copying during normal business hours.

c. Inspecting or obtaining copies of Application materials

Persons wishing to view or inspect any Application or award related materials must identify the items they wish to inspect and must make an inspection appointment by contacting Jesse Tanguileg at (916) 255-6008.

Persons wishing to obtain copies of Application materials may visit DHS or mail a written request to the DHS office identified below. The requestor must identify the items they wish to have copied and pay for a copy service. Materials will not be released from State premises for the purposes of making copies.

Request for Copies - RFA 04-35199
Department of Health Services
Office of Medi-Cal Procurement
Jesse Tanguileg
9800 Old Winery Place*
Sacramento, CA 95827

P.O. Box 997413, MS 4200
Sacramento, CA 95899-7413

*No U.S. Mail delivery at this address

7. Verification of Applicant information

By submitting an application, Applicants agree to authorize DHS to verify any and all information submitted in response to this RFA. This includes, but is not limited to verification of prior experience and the possession of other qualification requirements such as appropriate licenses and certificates.

8. DHS rights

In addition to the rights discussed elsewhere in this RFA, DHS reserves the following rights:

a. RFA corrections

1) DHS reserves the right to do any of the following up to the Application submission deadline:

a) Modify any date or deadline appearing in this RFA or the RFA Time Schedule.
b) Issue clarification notices, addenda, alternate RFA instructions, forms, etc.
c) Waive any RFA requirement or instruction for all Applicants if DHS determines that the requirement or instruction was unnecessary, erroneous or unreasonable.

d) Allow Applicants to submit questions about any RFA change, correction or addenda. If DHS allows such questions, specific instructions will appear in the cover letter accompanying the document.

To reduce State costs of mailing procurement corrections to persons and entities that do not intend to submit an application, DHS will mail or fax written clarification notices and/or RFA addenda only to those persons and entities that submit a timely Mandatory Letter of Intent and required attachments.

If DHS decides, just before or on the Application due date, to extend the submission deadline, DHS will notify persons or entities who submitted a timely Mandatory Letter of Intent and required attachments of the extension by fax or by telephone. DHS will follow-up any verbal notice in writing by fax or by mail.

b. Collecting information from Applicants

1) If deemed necessary, DHS may request an applicant to submit additional documentation during or after the Application review and evaluation. DHS will advise the Applicants orally, by fax or in writing of the documentation that is required and the time line for submitting the documentation. DHS will follow-up oral instructions in writing by fax or mail. Failure to submit the required documentation by the date and time indicated may cause DHS to deem an application non-responsive.

2) DHS, at its sole discretion, reserves the right to collect, by mail, fax or other method; the following omitted documentation and/or additional information:

a) Signed copies of any form submitted without a signature.
b) Data or documentation omitted from any submitted RFA attachment/form.
c) Information/material needed to clarify or confirm certifications or claims made by an applicant.
d) Information/material needed to correct or remedy an immaterial defect in an application.

3) The collection of Applicant documentation may cause DHS to extend the date for posting the Notice of Intent to Award. If DHS changes the posting date, DHS will advise the Applicants, orally or in writing, of the alternate posting date.

c. Immaterial Application defects

1) DHS may waive any immaterial defect in any Application and allow the Applicant to remedy those defects. DHS reserves the right to use its best judgment to determine what constitutes an immaterial deviation or defect.
2) DHS' waiver of an immaterial defect in an application shall in no way modify this RFA or excuse an applicant from full compliance with all Application requirements.

d. Correction of clerical or mathematical errors

DHS reserves the right, at its sole discretion, to overlook, correct or require an applicant to remedy any obvious clerical or mathematical errors occurring in an application.

e. Right to remedy errors

DHS reserves the right to remedy errors caused by:

1) DHS' office equipment malfunctions or negligence by agency staff; and
2) Natural disasters (i.e., floods, fires, earthquakes, etc.) or power outages.

f. No contract award or RFA cancellation

The issuance of this RFA does not constitute a commitment by DHS to award contracts. DHS reserves the right to reject all Applications and to cancel this RFA if it is in the best interests of DHS to do so.

g. Contract amendments after award

Should either party, during the term of this Contract, desire a change in the Contract, that change shall be requested in writing to the other party.

The other party will acknowledge receipt of the requested change for Contract amendment within ten (10) calendar days of receipt of the request. The party requesting any such change shall have the right to withdraw the request any time prior to acceptance or rejection by the other party. Any request shall set forth a detailed explanation of the reason and basis for the requested change, a complete statement of costs and benefits of the requested change and the text of the desired amendment to the Contract, which would provide for the change.

If the requested change is accepted and approved by the other party, the Contract shall be amended to provide for the change.

Except as otherwise expressly provided in this Contract, no oral understanding, term, or condition not incorporated in writing into this Contract is binding on any of the parties. The party responsible for implementing the change shall make the change within fifteen (15) calendar days of acceptance or at another mutually agreed upon date.

N. Contract Terms and Conditions

The Applicant must enter a written contract that may contain portions of the Applicant's Application such as the Scope of Work, Fiscal and Management Anti-Fraud Activities, Clinical Laboratory Compliance Program, standard contract provisions, the contract form, and the exhibits identified below. Other exhibits, not identified herein, may also appear in the resulting contract.

The exhibits identified in this section contain contract terms that require strict adherence to various laws and contracting policies. An applicant's unwillingness or inability to agree to the proposed terms and conditions shown below or contained in any exhibit identified in this RFA may cause DHS to deem an applicant non-responsive and ineligible for a contract award.

DHS reserves the right to use the latest version of any form or exhibit listed below in the resulting agreement if a newer version is available.

The exhibits identified below illustrate many of the terms and conditions that may appear in the final contract between DHS and the Applicant. Other terms and conditions, not specified in the exhibits identified below, may also appear in the resulting contract.

In general, DHS will not accept alterations to the Terms and Conditions, the Scope of Work, other exhibit terms/conditions, or alternate language that is proposed or submitted by a prospective Contractor. DHS may consider an application containing such provisions as "a counter Application" deeming such an application as non-responsive.

1. Contract Forms/Exhibits

	Exhibit Label	Exhibit Name
a.	Exhibit A1	Standard Agreement (1 page)
b.	Exhibit A	Scope of Work (6 pages)
c.	Exhibit B	Payment Provisions (1 page)
d.	Exhibit B	Attachment 1, Reimbursement Rates (18 pages)
e.	Exhibit C	Terms and Conditions (13 pages)
f.	Exhibit D	Notice to Licensed Practitioners Regarding the Medi-Cal Program (1 page)
g.	Exhibit E	Application Submitted by Clinical Laboratory (To be incorporated as an attached exhibit for each awarded contract.) (xx pages)

2. Unanticipated tasks

In the event unanticipated or additional work must be performed or qualifying requirements met that is not identified in this RFA, but in DHS' opinion is necessary to successfully accomplish the scope of work, DHS will initiate a contract amendment to add that work or requirement(s). All terms and conditions appearing in the final contract will apply to any additional work and requirement(s).

3. Resolution of language conflicts (RFA vs. final contract)

If an inconsistency or conflict arises between the terms and conditions appearing in the final contract and the proposed terms and conditions appearing in this RFA, any inconsistency or conflict will be resolved by giving precedence to the final contract.